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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,616	07/02/2001	Aprile L. Pilon	116142/00170	3118

31013 7590 02/14/2006

KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

LEE, BETTY L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.		Applicant(s)	
	09/898,616		PILON ET AL.	
	Examiner		Art Unit	
	Betty Lee, Ph.D.		1647	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Betty Lee, Ph.D. (3) Henry Ciltone, Reg 57206.
 (2) Brenda Brumback, Ph.D. (4) _____

Date of Interview: 08 February 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
 If Yes, brief description: _____

Claim(s) discussed: 35-55, 74-78 and 101-103.

Identification of prior art discussed: _____


Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: 1) IDS on CD will be mailed by Applicant 2) 112.2nd paragraph issues were discussed and how amendments to claims can overcome the rejections 3) The amendments for claim 49 and 55 under 103 were discussed 4) Double patenting issues of claims 35-55, 74-78, 101-103 were discussed 5) Applicant will cancel claims 35-41, 48-61 and 80-84 of copending Application No. 10187498 and file a terminal disclaimer to overcome the rejections.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



 Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

KRAMER LEVIN NAFTALIS & FRANKEL LLP

FROM: HENRY J. CITTONE
DATE: FEBRUARY 8, 2006
PHONE: 212-715-7780

FAX DEPARTMENT:
(212) 715-9191
SENDER'S FAX NUMBER:
212-715-8000

PLEASE DELIVER AS SOON AS POSSIBLE TO:

RECIPIENT	COMPANY	FAX NO.	PHONE NO.
1. Examiner Lee	USPTO	571-273-8152	

TOTAL NUMBER OF PAGES INCLUDING THIS PAGE: 7

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RE:

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

Claims 1-34 (canceled)

Claim 35. (original) A method of purifying rhUG comprising the steps of:

- a. providing a bacterial cell paste comprising bacterial cells capable of overexpressing rhUG;
- b. lysing the bacterial cell paste to form a supernatant;
- c. filtering the supernatant formed in step b through a first nominal molecular weight cut off (NMWCO) membrane to form a first permeate;
- d. concentrating the first permeate formed in step c by the use of a second NMWCO membrane;
- e. loading the concentrated permeate formed in step d onto an anion exchange column to form a first eluate;
- f. concentrating the first eluate formed in step e by the use of a third NMWCO membrane to form a second concentrate;
- g. loading the second concentrate formed in step f onto a Hydroxyapatite (HA) column to form a second eluate;
- h. separating host-derived proteins from the rhUG in the second eluate formed in step g to provide purified rhUG; and
- i. recovering the purified rhUG formed in step h.

Claim 36. (currently amended) The method of claim 35, wherein the rhUG expressed in the bacterial cells is a ~~synthetic gene~~ nucleic acid sequence selected from the group consisting of Seq. ID Nos. 1, 2, 3 and 4.

Claim 37. (original) The method of claim 35, wherein lysing comprises shearing.

Claim 38. (original) The method of claim 35, wherein between step b and step c, cell debris is removed by centrifugation.

Claim 39. (original) The method of claim 35, wherein the membrane of step b is about a 30K to 100K NMWCO membrane.

Claim 40. (original) The method of claim 39, wherein the filtering of step c comprises the use of a tangential flow filtration (TFF) system.

Claim 41. (original) The method of claim 35, wherein the membrane of step d is about a 5K NMWCO membrane.

Claim 42. (previously presented) The method of claim 41, wherein the anion exchange column of step e is a anion exchange column having an ionic capacity of between about 325 and about 475 μeq .

Claim 43. (previously presented) The method of claim 41, wherein the host-derived proteins of step h are separated with a Chelating Fast Flow (CSFF) resin column.

Claim 44. (original) The method of claim 43, wherein the CSFF resin column comprises copper.

Claim 45. (original) The method of claim 44, wherein after step h a positively charged membrane is placed downstream of the CSFF column forming a pass through substantially free of host derived proteins.

Claim 46. (previously presented) The method of claim 45, wherein the positively charged membrane is a filtration membrane.

Claim 47. (original) The method of claim 35, wherein the second eluate is diafiltered through about a 30K NMWCO membrane.

Claim 48. (original) The method of claim 35, wherein the rhUG recovered in step i is substantially free of aggregates.

Claim 49. (currently amended) A method of purifying rhUG comprising the steps of:

- a. providing bacterial cells capable of overexpressing rhUG;
- b. lysing the bacterial cells to form a supernatant liquid;
- c. filtering the liquid through a molecular weight cut off (NMWCO) membrane;
- d. loading the liquid onto an ion exchange column;

- e. separating host-derived proteins from the rhUG to provide purified rhUG; and
- f. recovering the purified rhUG

wherein the level of endotoxin in said rhUG is less than 5 EU/mg.

Claim 50. (currently amended) The method of claim 49, wherein the rhUG expressed in the bacterial cells is a ~~synthetic gene~~ nucleic acid sequence selected from the group consisting of Seq. ID Nos. ~~1-4~~ 1, 2, 3 and 4.

Claim 51. (original) The method of claim 49, wherein the filtering of step c comprises the use of a tangential flow filtration (TFF) system.

Claim 52. (previously presented) The method of claim 49, wherein the ion exchange column of step d is a anion exchange column having an ionic capacity of between about 325 and about 475 μeq .

Claim 53. (previously presented) The method of claim 49, wherein the host-derived proteins of step e are separated with a Chelating Fast Flow (CSFF) resin column.

Claim 54. (original) The method of claim 49, wherein the rhUG recovered in step f is substantially free of aggregates.

Claim 55. (currently amended) A method of producing a pharmaceutical grade rhUG drug substance comprising the steps of:

- a. providing a bacterial expression system capable of expressing rhUG;
- b. inoculating a fermenter with an inoculum comprising the bacterial expression system to form a fermentation culture;
- c. adding an induction agent to the fermentation culture to induce the expression of rhUG by the bacterial expression system;
- d. harvesting the rhUG expressed in step c; and
- e. purifying the rhUG harvested in step d, wherein the purifying step comprises the use of at least one filtration step and at least one exchange column wherein the rhUG produced is of pharmaceutical grade and wherein the level of endotoxin in said rhUG is less than 5 EU/mg.

Claim 56-73. (canceled)

Claim 74. (~~previously presented~~ currently amended) The method of claim 35 further comprising steps for determining the purity of recombinant human uteroglobin comprising,

- (a) taking samples ~~of intermediates~~ at each step within the process of claim 35 and
- (b) analyzing ~~the process intermediates~~ said samples to determine purity relative to unpurified recombinant human uteroglobin or
- (c) analyzing ~~the process intermediates~~ said samples to determine purity relative to purified recombinant human uteroglobin taken from a step of claim 35 which precedes the step within the process of claim 35 from which said samples ~~of intermediates~~ were taken.

Claim 75. (original) The method of claim 74, wherein process intermediates are analyzed by SDS-PAGE.

Claim 76. (original) The method of claim 74, wherein process intermediates are analyzed by rhUG ELISA.

Claim 77. (original) The method of claim 74, wherein process intermediates are analyzed by LAL.

Claim 78. (original) The method of claim 74, wherein process intermediates are analyzed for protein content.

Claim 79-100. (canceled)

Claim 101. (previously presented) The method of claim 35 wherein said purified rhUG is of pharmaceutical grade.

Claim 102. (previously presented) The method of claim 49 wherein said purified rhUG is of pharmaceutical grade.

Claim 103. (previously presented) The method of claim 74 wherein said purified rhUG is of pharmaceutical grade.